a1 cont'd

expression of endogenous gene, (g) providing a means for studying the effects of specific proteins in differentiated and undifferentiated tissue, (h) generating an animal model system for human diseases, and (i) inducing wound healing via the production of specific growth factor genes.

a2

4. (Amended) A method according to claim 1 wherein said plasmid expression vector comprises DNA sequences selected form the group consisting of a DNA sequence claiming enhancer/promoter and other regulatory elements, a DNA sequence which can be transcribed into an RNA which RNA can be (a) translated into a protein, (b) includes a transcriptional termination signal, and (c) may include coding sequences for a signal peptide which allows a protein to be exported from the cell, a DNA sequence which targets a gene for incorporation into the genome, a DNA sequence which directly replicates in eukaryotic cells, and a plasmid sequence which allows DNA replication in prokaryotic cells.

5. (Amended) A method according to claim 4 wherein said DNA sequence is constructed using an enhancer/promoter component, a termination signal, and a signal peptide coding sequence from different genes which are combined to directly express in a specific manner.

6. (Amended) A method according to claim 2 wherein the enhancer/promoter sequence is a naturally occurring promoter/enhancer.

7. (Amended) A method according to claim 4 wherein the enhancer/promoter is composed of a generic TATA box and binding sites for the E2 transcription factor and said enhancer/promoter is coded by the papillomavirus genome, wherein said enhancer/promoter is expressed in cells capable of expressing the E2 protein from papillomavirus.

a3

11. (Amended) The method of claim 1, wherein said plasmid expression vector is expressed in a living organism at about 1 to about 3 cm distant from the site of injection.

a4

19. (Amended) A method for obtaining transient gene expression or stable gene expression in mammary tissue comprising: exogenously administering a plasmid expression vector, to mammary tissue of a living organism, using a jet injector, wherein said plasmid expression vector is expressed in the living organism.

21. (Amended) A method of immunization comprising the steps of jet injecting an effective amount of a plasmid expression vector, to transform differentiated somatic cell tissue of a living organism selected from the group consisting of skin, muscle, fat and mammary tissue, wherein said plasmid expression vector is expressed in the living organism, and wherein DNA expressed from said plasmid expression vector immunizes said living organism.

Please add the following new claims:

22. (New) A method according to claim 2 wherein the enhancer/promoter sequence is the HCMVIE1 promoter/enhancer sequence.

23. (New) A method according to claim 2 wherein the enhancer/promoter sequence is an enhancer/promoter sequences constructed using specific DNA elements, which mediate binding by specific transcription factors to directly express only in specific cell types.

REMARKS

The Present Invention

The present invention pertains to a method for obtaining gene expression in somatic cell tissue and a method for immunization, by administering a plasmid expression vector using a jet injector.

The Pending Claims

Claims 1-23 are currently pending, of which claims 1-12, 19, 20, 22 and 23 are directed to the method for obtaining gene expression in somatic cell tissue and claim 21 is directed to the method for immunization.

The Office Action

The Office has maintained the election of species requirement. Claims 13-18 have been withdrawn from further consideration, as being drawn to a non-elected invention. Claims 1-12 and 19-21 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. Claims 1-12 and 19-21 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 1-12 and 19-21 have been rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting. Reconsideration of these rejections is hereby requested.